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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/561,425

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EXAMINER

RUSSEL, JEFFREY E

ART UNIT

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1654

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/561,425	Applicant(s) GRIFFIN ET AL.	
	Examiner Jeffrey E. Russel	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12, 14-33, 37, 38 and 41-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 20, 28-33, 37, 38 and 41-44 is/are rejected.
- 7) ☒ Claim(s) 9-12, 14-19 and 21-27 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 December 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>20071101</u> . | 6) <input type="checkbox"/> Other: _____ |

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1. The declaration under 37 CFR 1.63 filed November 19, 2007 gives an incorrect filing date for foreign priority document GB 2003-0314262.7. The correct filing date for this foreign priority document is June 19, 2003. However, the foreign priority document is otherwise correctly identified in the declaration, and the filing date for the foreign priority document is corrected in the Application Data Sheet filed February 10, 2009. Accordingly, the declaration under 37 CFR 1.63 filed November 19, 2007 is approved.
2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.
3. The drawings are objected to because in Figure 23(A), the words present in the panels are illegible. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

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4. The abstract of the disclosure is objected to because of the use of the legal phraseology “said” at line 4. The Abstract should be amended to recite formula I, so that there is context for the variables currently defined in the Abstract. Finally, the Abstract would benefit from deletion of phrases which can be implied, e.g., “The present invention relates to”. Correction is required. See MPEP § 608.01(b).

5. The disclosure is objected to because of the following informalities: In the preliminary amendment to the specification filed December 19, 2005, line 3, “British” is misspelled. There is no Brief Description of the Figures as is required by 37 CFR 1.74. If pages 24-29 are intended by Applicants to serve as the Brief Description of the Figures, an appropriate heading should be inserted at the beginning of this section. If page 29 is intended by Applicants to serve as the Brief Description of Figure 26, then the paragraph should be amended to refer separately to Figures 26(A) and 26 (B). See MPEP 608.01(f), page 600-81, column 2, first full paragraph (Rev. 7, July 2008). Appropriate correction is required.

6. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 38 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. A “use” is not a statutory class of invention.

7. Claims 1-8, 20, 28-33, 37, 38, and 41-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The meaning of the term “derivative” at claim 1, last line, is unclear. It is not clear what degree of structural and/or functional similarity a compound must have with Applicants' claimed compounds in order for the compound to be

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considered a "derivative" of Applicants' claimed compounds and therefore embraced within the scope of Applicants' claims. The term "derivative" is not defined either in Applicants' specification or in the art. It is not clear why the phrase "or an N-substituted derivative thereof" at claim 3, line 2, is enclosed within parentheses. If the phrase is intended to constitute a claim limitation, the parentheses should be removed. It is also not clear if "N-substituted" refers to the alpha-amino nitrogen of the glutamine, or to the nitrogen atom that forms part of the side chain of the glutamine. At claim 8, line 2, the second structure is unclear because neither carbon atom has all of its valences specified. If Applicants intended to recite an ethyl group, the correct structure for this group is $-\text{CH}_2\text{CH}_3$. The compound formula recited in claim 20 is unclear, because the structure of the $\text{NH}_2\text{F}_3\text{CO}_2\text{H}$ group can not be determined. No atom is present in the group, or in the formula, to which 3 fluorine atoms can be attached. Claim 33, lines 1-2, indicates that a Markush group of protected amino acid N-hydroxy-succinimide esters is defined. However, the last protected amino acid ester listed in claim 33 is a para-nitrophenyl ester. The Markush group set forth in claim 33 is therefore unclear as to what members are embraced. Claim 37 is indefinite because lines 5-6 of the claim do not recite to what or to whom the composition is being administered. The positive process step does not mention the patient referred to at line 1 of the claim. The phrase "(such as chronic inflammatory diseases)" at claim 37, line 5, is unclear as to whether the inflammation is to be limited to chronic inflammatory diseases. Assuming that Applicants do not intend to limit the inflammation to be treated to chronic inflammatory diseases, it is not clear why the parenthetical phrase is included in the claim. It is suggested that the parenthetical phrase could be deleted and made the subject matter of a further dependent claim. Claim 38 is dependent upon canceled claim 35. There is no

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antecedent basis in the claims for the phrase “the medicament” in claim 38. None of the preceding claims use the term “medicament”. Claims 41 and 44 are indefinite because they are drawn to a method, but do not recite any positive process steps. Note that claim 41 does not depend upon any other claim, and does not require, e.g., administration of a compound, or administration of a compound of formula I.

8. Claims 7-12, 14-27, 33, 37, and 38 are objected to because of the following informalities:

At claim 7, line 1, “compounds” should be changed to “compound”. At claim 8, line 2, a space should be inserted between “are” and “-CH₃”. Claims 9-12 and 14-27 do not end with periods.

At claim 33, line 4, “alaninal” should be changed to “alanine”. At claim 37, lines 3 and 4, “fibrosis” is repeated, and “scarring” is repeated. One of each pair should be deleted. At claim 38, line 1, “Claims” should be changed to “Claim”. Appropriate correction is required.

9. Claim 33 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The last protected amino acid ester listed in claim 33 is a para-nitrophenyl ester. However, claim 33 depends upon claim 31, which is limited to protected amino acid N-hydroxysuccinimide esters. Accordingly, claim 33 embraces methods of reacting compounds which are not embraced by claim 31, upon which claim 33 depends, and therefore claim 33 is an improper dependent claim.

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-8, 28, 29, and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by the European Patent Application 411,895. The European Patent Application '895 teaches peptidic thio-imidazol compounds, and hydrobromide salts thereof, which inhibit transglutaminase and are used pharmaceutically in order to inhibit thrombosis. See, e.g., page 3, lines 38-39, and claims 1-11. The compounds of the European Patent Application '895, and Applicants' compounds of formula I, are peptidic, comprise a thio-imidazol group, and inhibit transglutaminase. Therefore the compounds of the European Patent Application '895 are deemed to be derivatives of Applicants' compounds of formula I in view of their structural and functional similarity. Note that Applicants have not provided a definition of "derivative" which would distinguish over the compounds of the European Patent Application '895, and "derivative" is not defined in the art so that the compounds of European Patent Application '895 are excluded from the scope of Applicants' claims.

12. Claims 9-12, 14-19, and 21-27 would be allowable if rewritten to overcome the claim objections set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

If claim 1 was to be amended so as to delete the "derivative thereof" language from the claim, then claim 1, and the claims dependent upon claim 1, would be novel and unobvious over the European Patent Application 411,895 applied above, or any of the other prior art of record. The prior art of record does not teach or render obvious compounds having the structure of Applicants' formula I.

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13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jeffrey E. Russel/
Primary Examiner, Art Unit 1654

JRussel
August 26, 2009